

## REMARKS

The present invention provides RNase P polypeptides and methods for identifying antibacterial agents using these polypeptides.

Claims 1, 2, 8-11, and 13-40 are pending in this case. Claims 22-28 and 30-40 are withdrawn from consideration. Claims 2, 16, and 20 are rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 2, 8-11, 13-21, and 29 are rejected under 35 U.S.C. § 112, first paragraph. Each of these rejections is addressed below in the order that it appears in the Office action.

### Support for the Amendments

Claim 1 has been amended to specify that the claimed RNase P protein sequence, when aligned using the ClustalW program with the *E. coli* RNase P protein, has at least nine of the twenty specified amino acids from the *E. coli* RNase P protein. Support for this amendment can be found throughout the specification, for example, at page 7, lines 1 to 8, and page 10, lines 21 to 25. Claim 1 has also been amended to delete several of the organisms that were inadvertently included more than once. These amendments do not add new matter.

The specification has been amended to specifically list the sequences and their GenBank or SEQ ID NOs that are incorporated, in the application as filed, by reference to Brown, *Nucleic Acids Research* 27:314 (1999), the Ribonuclease P Database described

therein, EP 0 811 688 A2, and WO 99/11653. Support for this amendment can be found in the references cited in the specification, for example, at page 7, lines 17 to 22. As attested to in the Declaration of Vicki L. Healy, submitted on October 11, 2002 (a copy of which is attached hereto), the protein sequences for each of the RNase P protein subunits listed in claim 1, except for *Staphylococcus aureus* and *S. pneumoniae*, were available in the RNase P Database of James W. Brown on March 1, 2000. The sequence for the RNase P protein subunits of *Staphylococcus aureus* and *S. pneumoniae* are provided by reference to the patent applications also cited above.

The specification has also been amended to include the amended sequence listing, submitted herewith, which includes SEQ ID NOs: 92 to 98 as set forth in Table 1, presented above.

#### Objection to the Drawings and the Specification

The Examiner objects to the substitute Figure 1 submitted with the amendment filed on June 24, 2004, for lacking the proper "Replacement Sheet" label. Applicants have amended Figure 1 to include this label in compliance with 37 C.F.R. § 1.121(d). This objection can now be withdrawn.

Rejection of claims 2, 16, and 20 under 35 U.S.C. § 112, second paragraph

Claims 2, 16, and 20 were rejected under 35 U.S.C. § 112, second paragraph, for reciting non-elected embodiments of the invention. As noted by the Examiner, applicants maintain that claims 2, 16, and 20 need not be limited to the elected species at this time. In the event that a generic claim is allowed, applicants assert that claims to the remaining species, which are written in dependent form, or which otherwise include all the limitations of the allowed generic claim should be considered as provided by 37 CFR § 1.141 and MPEP § 809.02(a). Applicants understand that the Examiner has indicated that this rejection will be maintained until a generic claim is allowed or the claims are restricted to the elected species.

Rejection of claims 1, 2, 8-11, 13-21, and 29 under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 8-11, 13-21 and 29 are rejected under 35 U.S.C. § 112, first paragraph, for an asserted lack of an adequate written description and an asserted lack of enablement. Each of these rejections is discussed in detail below.

*Written Description*

Claims 1, 2, 8-11, 13-21 and 29 are rejected under 35 U.S.C. § 112, first paragraph, for an asserted lack of an adequate written description. In view of the present amendments, applicants respectfully request that this rejection be withdrawn.

The Examiner states that the list of the excluded polypeptides incorporated by reference on page 7, lines 17-22 of the specification, is considered essential material and is therefore improperly incorporated. In accordance with MPEP § 608.01(p), applicants have amended the specification to include the material incorporated by reference. Applicants also enclose a Declaration of Kristina Bieker-Brady, Ph.D., stating that the amendatory material consists of the same material incorporated by reference.

Applicants have inserted Tables 1 and 2 into the specification, which include a list of the RNase P polypeptide sequence with SEQ ID NO or GenBank accession numbers for each organism excluded in claim 1. All of the RNase P proteins from the organisms listed were provided by incorporation by reference, in the application as filed, to Brown, *Nucleic Acids Research* 27:314 (1999), the Ribonuclease P Database described therein, EP 0 811 688 A2, and WO 99/11653 (see page 7, lines 17-22 of the specification). Applicants respectfully point out that the excluded RNase P polypeptide sequence for each excluded organism is now clearly identified in the specification either by GenBank accession number or by a SEQ ID NO associated with a sequence provided in the specification. These sequences were all available in the Ribonuclease P Database and in EP 0811 688 A2 and WO 99/11653 at the time of filing as attested to by Dr. Healy in the Declaration submitted on October 11, 2002. In view of this amendment to the specification, applicants respectfully request that this basis for the rejection be withdrawn.

Applicants note that the following organisms previously included in claim 1 have been deleted from the claim: *B. burgdorferi*, *C. burnetii*, *C. pneumoniae*-2, *C. trachomatis*, *H. pylori*-48, *M. leprae*, *M. luteus*, *M. bovis*, *Pseudanabaena*-6903, *R. prowazeki*, *S. bikiniensis*, *Synechocystis* 6803. These organisms were inadvertently included more than once in the claim. Applicants note that the RNase P polypeptide from these organisms is identical to the sequence from the same organism listed earlier in the claim.

The Examiner further rejects the claims because, according to the Examiner, it is not known to which RNase P the sequences must be aligned and what program should be used for such an alignment. Applicants have amended the claim to specify that an isolated polypeptide of the invention has, when aligned with the *E. coli* RNase P protein sequence using the ClustalW program, at least nine of the specified twenty amino acids from the *E. coli* RNase P protein sequence. In view of this amendment, this basis for the rejection can be withdrawn.

#### *Enablement*

Claims 1, 2, 8-11, 13-21, and 29 are rejected under 35 U.S.C. § 112, first paragraph, for an asserted lack of enablement. Applicants disagree and respectfully request that this rejection, as applied to the present claims, be withdrawn.

The Examiner maintains this rejection because, “claim 1 does not require the

alignment to a known RNase P sequence, nor does it state that this alignment must be by the ClustalW program.” As stated above, applicants have amended the claim to specify that an isolated polypeptide of the invention will have, when aligned with the *E. coli* RNase P protein sequence using the ClustalW program, at least nine of the specified twenty amino acids from the *E. coli* RNase P protein sequence. In view of this amendment, this rejection can be withdrawn.

### REMARKS

In summary, applicants submit that the claims are now in condition for allowance and such action is respectfully requested.

Enclosed are a Petition to extend the period for replying to the final Office action for three months, to and including April 4, 2005, and a check in payment of the required extension fee. Also enclosed is a Notice of Appeal, in which applicants respectfully appeal the final rejection of the pending claims.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

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